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# **The Challenges of Consulting the Public on Science Policy: Examining the development of European risk assessment policy for genetically modified animals**

## **Abstract**

With the growing importance of public engagement in science policy-making and declining levels of public trust in food production, the European Food Safety Authority (EFSA) has attempted to embed ‘good governance’ approaches to strengthen scientific independence and open-up risk decision-making, which include the use of public consultations. However ‘opening-up’ of risk assessment policies reveals some tensions, namely: balancing the goals of scientific excellence and transparency; protecting science from interests; addressing value judgments; limited opportunities to debate ethical and social issues. EFSA’s development of risk assessment policy for genetically modified animals is used as a case study to analyse these tensions. This analysis suggests that in order to fulfil good governance commitments and maintain trust in risk governance closer cooperation between EFSA and the European Commission is required to provide ‘space’ for debating the broader risk management issues. This publically-accessible space may be needed alongside rather than instead of EFSA’s consultation.

## **1. Introduction**

With the growing importance of public engagement in science policy-making and declining levels of public trust in food production, the European Food Safety Authority (EFSA) has attempted to strengthen scientific independence and open-up risk decision-making through the use of public consultations. However ‘opening-up’ risk assessment policies reveals some tensions, namely: balancing the goals of scientific excellence and transparency; protecting

science from interests; addressing value judgments; and limited opportunities to debate ethical and social issues.

The role of publics in the development of science policy has shifted considerably in the last twenty years, from one where publics are deemed to have a deficit in knowledge or understanding and as such need education about science, to one in which publics are valuable contributors to science policy development (Burgess, 2014; Jones, 2014). In response to this shift in thinking about the role of publics and the democratic deficit resulting from various food and agricultural crises that were seen in Europe in the 1990s, the European Commission ('Commission') initiated a new 'good governance' agenda that involved opening-up science policy-making to the public. At the turn of the century, the Commission's White Paper on European Governance set out an agenda to increase legitimacy and rebuild trust in expert advice and European governing institutions more broadly, including those with risk assessment and management responsibilities (European Commission, 2001). An outcome of this White Paper was the General Food Law Regulation (EC Regulation No 178, 2002) which established EFSA in 2002 to provide scientific advice to the Commission on food safety matters and take responsibility for the risk assessment<sup>1</sup> and communication functions of risk analysis. Since its establishment, EFSA has played a significant role in developing European risk assessment policy<sup>2</sup> through its 'Guidance' documents which explain the principles behind the procedures and approaches to risk assessment and specify the information and data required for risk assessors, risk managers and applicants (Vos & Wendler, 2006). EFSA embedded this notion of good governance with a specific focus on strengthening the independence of scientific advice and opening-up risk assessment policy to the public through consultations.

Traditionally, decisions concerning risk assessment policy have been left to scientific experts with the public participation literature suggesting public consultations are more appropriate for risk management decisions than for risk assessments policy (Rowe & Frewer, 2000). In this context, EFSA's public consultations should be recognised as innovative. However, opening-up a scientific body to public involvement has resulted in greater levels of scrutiny and in turn has triggered debate about a number of possible tensions in the food risk characterisation and management process at a policy-level. Through an analysis of the published literature, this work identifies four tensions arising from opening-up science policy, particularly risk assessment policy to public or stakeholder involvement:

1] A tension is observed between the goals of **scientific excellence and openness and transparency**, particularly when public consultations are used to achieve both goals. Opening up science policy-making to public and stakeholder involvement brings a broader range of knowledge that may challenge traditional notions of scientific excellence and expertise, potentially allowing values to shape scientific outputs and therefore undermine these notions of scientific excellence (Scientific Committee on Health and Environmental Risks, Scientific Committee on Emerging and Newly Identified Health Risks, and Scientific Committee on Consumer Safety, 2013; Klintman & Kronsell, 2010; Bengtsson & Klintman, 2010; Steffek & Ferretti, 2009; Oels, 2006, Waterton & Wynne, 2004). Current management approaches limit the 'opening up' of policy-making, favouring scientific excellence over a broader inclusiveness and therefore such processes are not responsive to public and stakeholder expectations.

2] When endeavouring to ensure that scientific advice in policy processes is at the cutting edge of knowledge advances and technology development, yet is independent and protected from interests, particularly single issue interests, tensions emerge. Opening up science policy

to public and stakeholder input can challenge the **independence of scientific advice** (Klintman & Kronsell, 2010). Management approaches that strive to open-up the process but only facilitate technological input and not insights from other stakeholders can be subject to criticism regarding access bias and independence. EFSA has recently been criticised for such conflicts, which are more apparent as the organisation strives to open-up.

3] The tension between acknowledging **value judgements in risk assessment** that can be challenged and traditional notions of science as a value-free enterprise can be difficult to manage in an open consultation process and can result in even the very framing of any risk assessment being challenged (Begley, 2013; Boyd, 2013; Wickson & Wynne, 2012; Finardi, Pellegrini & Rowe, 2012; Fanelli, 2012, 2009; Meghani, 2009; Klintman & Kronsell, 2010; Wandall, 2004; National Research Council, 1996; Kunreuther & Slovic, 1996; Brunk, Haworth & Lee, 1992). EFSA has at times denied the existence of values in risk assessment and management approaches have limited opportunities to discuss them.

4] The tension between what is deemed as the scientific characterisation of a risk (science) and then how that risk ought to be managed (ethics, politics, etc.) in the broader risk governance framework can be seen to be controversial and contested. This is often set out in statutory terms as the division between risk assessment and risk management. When scientific risk assessment policy is developed in isolation from the broader risk management policy, a forum to discuss the **ethical and social issues associated with risk management** can be absent and this in turn causes tension (Brunk & Hartley, 2012; Gaskell, Kronberger, Fischler, Hampel & Lassen, 2007; Wandall, 2004). Opening-up only part of the risk process to a limited public consultation can exacerbate existing frustrations regarding the lack of consultation on and consideration of ethical and social dimensions.

Despite calls for further research and insights from the social sciences on participation in risk assessment policy (Shepherd, 2008), there is a paucity of case-based investigations of public consultations employed in the development of risk assessment policy. Here, we analyse the four tensions identified above through the illustrative case of EFSA's development of risk assessment policy for genetically modified (GM) animals. EFSA's establishment has been an important step along the 'good governance' road for food risk management but some of the tensions that are discussed here may impact on the long term legitimacy or perceived legitimacy of EFSA's risk assessment processes not only for GM animals but the governance of GM animals in the EU more broadly. This analysis suggests that in order to fulfil good governance commitments and maintain trust in risk governance closer cooperation between EFSA and the European Commission is required to provide 'space' for debating the broader risk management issues. This publically-accessible space may be needed alongside rather than instead of EFSA's consultation. The study provides useful insights for future policy development at EFSA and holds valuable lessons for wider efforts to consult the public on science policy.

The case of GM animals was selected on the grounds that it is a recent example of EFSA's risk assessment policy, announced in May 2013 and, given the controversy around risk governance decisions for animal cloning (Brunk & Hartley, 2012), GM animal policy was likely to involve important governance and ethical issues, particularly concerning animal welfare. Further, this case allowed access to the data from the public consultations through publically accessible documents on EFSA's website (accessed between May 2013 and March 2014). Research was conducted through documentary analysis of the resources listed in Table 1, including EFSA's corporate and policy documents, meeting minutes, guidance documents and open access 'comments' submitted through the public consultation processes.

**Table 1. Documentary analysis: Key documents analysed**

Year	Author	Document
2013	EFSA	Guidance on the Environmental Risk Assessment of Genetically Modified Animals, Scientific Opinion, <a href="http://www.efsa.europa.eu/en/efsajournal/doc/3200.pdf">http://www.efsa.europa.eu/en/efsajournal/doc/3200.pdf</a>
2013	EFSA	Outcome of the Public Consultation on the Draft Scientific Opinion of the Scientific Panel on Genetically Modified Organisms Providing Guidance on the Environmental Risk Assessment of Genetically Modified Animals, <a href="http://www.efsa.europa.eu/en/supporting/doc/428e.pdf">http://www.efsa.europa.eu/en/supporting/doc/428e.pdf</a>
2012	EFSA	Guidance on the Risk Assessment of Food and Feed from Genetically Modified Animals and on Animal Health and Welfare Aspects, <a href="http://www.efsa.europa.eu/en/efsajournal/doc/2501.pdf">http://www.efsa.europa.eu/en/efsajournal/doc/2501.pdf</a>
2012	EFSA	Outcome of the public consultation on the Draft Scientific Opinion of the Scientific Panels on Genetically Modified Organisms and on Animal Health and Welfare on the Guidance on the Risk Assessment of Food and Feed from Genetically Modified Animals and on Animal Health and Welfare Aspects, <a href="http://www.efsa.europa.eu/en/supporting/doc/226e.pdf">http://www.efsa.europa.eu/en/supporting/doc/226e.pdf</a>
2012	EFSA	Draft Guidance on the Environmental Risk Assessment of Genetically Modified Animals, <a href="http://www.efsa.europa.eu/en/consultationsclosed/call/120621.pdf">http://www.efsa.europa.eu/en/consultationsclosed/call/120621.pdf</a>
2011	EFSA	Draft Guidance on the risk assessment of food and feed from genetically modified animals including animal health and welfare aspects, <a href="http://www.efsa.europa.eu/en/consultationsclosed/call/110810.pdf">http://www.efsa.europa.eu/en/consultationsclosed/call/110810.pdf</a>
2011	EFSA	EFSA GMO Unit Report of the GM mammals and birds workshop, 29 October 2010, <a href="http://www.efsa.europa.eu/en/search/doc/149e.pdf">http://www.efsa.europa.eu/en/search/doc/149e.pdf</a>
2010	EFSA	EFSA GMO Unit Report of the GM fish workshop, 4 February 2010, <a href="http://www.efsa.europa.eu/en/search/doc/150e.pdf">http://www.efsa.europa.eu/en/search/doc/150e.pdf</a>
2010-2013	EFSA Working Groups, GMO and AHAW Panels	Minutes of meetings <a href="http://www.efsa.europa.eu/en/gmo/gmowgs.htm">http://www.efsa.europa.eu/en/gmo/gmowgs.htm</a> <a href="http://www.efsa.europa.eu/en/panels/gmo.htm">http://www.efsa.europa.eu/en/panels/gmo.htm</a> <a href="http://www.efsa.europa.eu/en/panels/ahaw.htm">http://www.efsa.europa.eu/en/panels/ahaw.htm</a>
Various	EFSA	Key corporate/policy documents, <a href="http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm">http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm</a>

The following section (Section 2) introduces the case of risk assessment policy development for GM animals, briefly laying out the policy process and the public consultations. Section 3 examines each of the four tensions in the case of EFSA's development of a risk assessment policy for GM animals. Lastly, Section 4 concludes that while EFSA's public consultation policy tool presents a valuable and innovative opportunity to debate the values embedded in risk assessment in a way that can strengthen risk governance, it does not appear fit for purpose as it limits the type of knowledge that inform risk assessment, is out of step with public understandings of risk and the open governance agenda. Closer cooperation between EFSA and the Commission on public consultation is required to allow the European public to provide input on the full range of issues related to risk governance of GM animals alongside EFSA's public consultation on the scientific aspects of risk governance.

## 2. The case study

The use of GM animals in open field trials and the marketing and consumption of GM animals are governed by Directive 2001/18/EC and Regulation (EC) No 1829/2003.<sup>3</sup> In 2007, the Commission instructed EFSA to develop risk assessment policy for potential applicants who want to release a GM animal into the European environment. Although no GM animal has been approved in Europe, scientific experts predict that the first GM animals approved for release in Europe will be GM insects used as integrated pest management tools in agricultural production and that these animals could be on the European market by the end of this decade (Environment Agency Austria, 2010).<sup>4</sup>

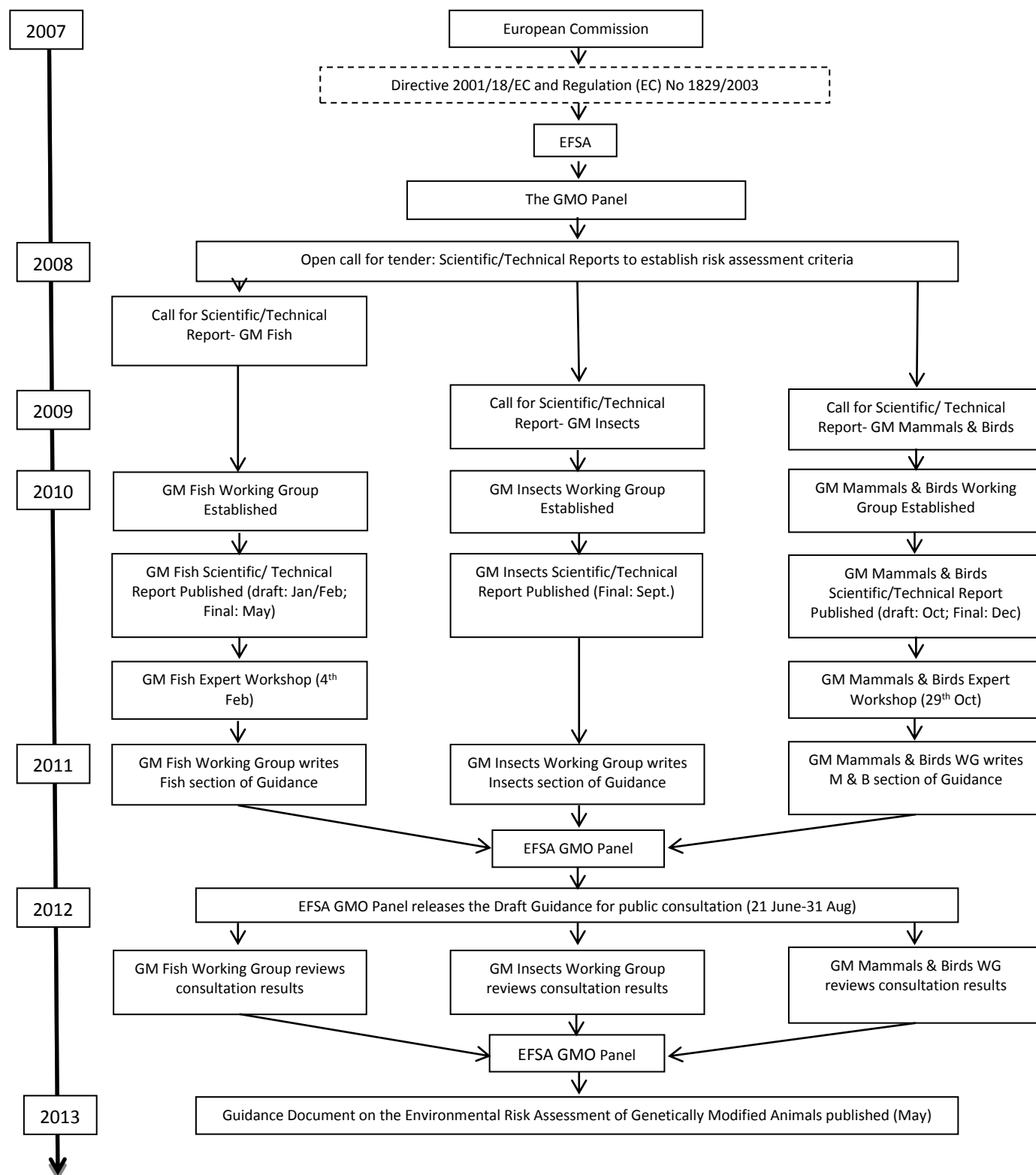
EFSA developed two Guidance documents for potential applicants that established the risk assessment policy for GM animals. In December 2011, EFSA adopted the '*Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects*' (EFSA, 2012c). In 2013, EFSA adopted the '*Guidance on the environmental risk assessment of genetically modified animals*' (EFSA, 2013a). In line with EFSA's policies, the process of developing the two Guidance documents included public consultations with the aim to increase the quality and effectiveness of public policy outcomes and build public trust by 'opening up' risk assessment (EFSA, n.d.).

In 2008, EFSA triggered the formal process of developing a risk assessment policy for GM animals. Figure 1. shows the process of developing the *Guidance on the environmental risk assessment of genetically modified animals*. This process included an open call for Scientific/Technical Reports to establish the environmental risk assessment criteria. EFSA's expert Genetically Modified Organisms (GMO) and Animal Health and Welfare (AHAW) Panels and various working groups used these reports<sup>5</sup>, Codex Alimentarius Commission guidelines, other relevant background information and the comments garnered through expert



workshops formed the information basis for the draft Guidance documents. Subsequently, EFSA held public consultations for each of the two Guidance documents.

**Figure 1. The process of developing the *Guidance on the environmental risk assessment of genetically modified animals***



The first public consultation was held from 10 August to 30 September 2011 on the draft '*Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare*'. The second consultation ran from 12 June to 31 August 2012 on the draft '*Guidance on the environmental risk assessment of genetically modified animals*'. The public was invited to comment on the draft documents although comments would not be taken into account if they related to "policy or risk management aspects, which is out of the scope of EFSA's activity" (EFSA, 2012a, p. 10). In the case of the risk assessment of food, feed and animal health and welfare, EFSA documents 341 comments from 29 interested parties (although it states that it received comments from 32 parties) (EFSA, 2012a). In the case of the environmental risk assessment, EFSA received 720 comments from 35 interested parties. Tables 2 and 3 document the participants in each of the consultations. These interested parties include stakeholders and individual members of the public. EFSA considered all comments that fell within its remit. Comments related to the ethical and social aspects of the Guidance documents were not addressed (EFSA, 2012a).

**Table 2. Participants in the public consultation on the environmental risks of GM animals**

Environmental risk assessment				
Government department / agency	University/ research org	Industry	Public interest group	Individual
(1) Advisory Committee on Releases to the Environment (GBR) (2) Federal Office of Consumer Protection and Food Safety (DEU) (3) Federal Agency for Nature Conservation (DEU) (4) Belgian Biosafety Advisory Council (BEL) (5) Umweltbundesamt on behalf of Austrian Ministry of Health (AUT) (6) National Commission on Biosafety (ESP) (7) Netherlands Commission on Genetic Modification (COGEM) (NDL) (8) Ministry of Infrastructure and the Environment (NDL) (9) Environment Canada (CAN)	(10) Max-Planck-Institut für Evolutionsbiologie (DEU) (11) Univ. Perugia (ITA) (12) University Boku (PRT) (13) GenØk–Centre for Biosafety (NOR)	14) Oxitec Ltd (GBR)	(15) GeneWatch UK (GBR) (16) Food & Water Europe (GBR) (17) GM Freeze (GBR) (18) Soil Association (GBR) (19) TiK (GBR) (20) Testbiotech (DEU) (21) European Beekeeping Coordination (BEL) (22) Agernova (ITA) (23) Association Soleil en Tête (FRA) (24) Center for Food Safety (USA) (25) Friends of the Earth US (USA)	(26) n/a (GBR) (27) Self Employed (GBR) (28) None (GBR) (29) Public (GBR) (30) Private Individual (GBR) (31) Personal (GBR) (32) none (IRL) (33) Individual connected (FRA) (34) N/A (FRA) (35) Self (USA)

Note: Participants organised by type using names and geographical locations provided by EFSA (2013b).

**Table 3. Participants in the public consultation on the risks from food and feed from GM animals and on animal health and welfare**

Risk assessment of food and feed from GM animals and on animal health and welfare				
Government department / agency	University/research org	Industry	Public interest group	Individual
(1) Ministry of Rural Development of Hungary (HUN) (2) Federal Office of Consumer Protection and Food Safety (DEU) (3) Federal Agency for Nature Conservation (DEU) (4) The Norwegian Biotechnology Advisory Board (NOR) (5) U.S. Food & Drug Administration (USA) (6) Norwegian Scientific Committee for Food Safety (NOR) (7) Food Standards Agency (GBR) (8) French Agency for Food, Environmental and Occupational Health & Safety (FRA) (9) BAC (Scientific Advisory Body Secretariat) (BEL)	(10) University of Nebraska Lincoln (USA) (11) CRIIGEN and University of Caen (FRA) (12) Institute of Food Science and Technology (GBR) (13) European Network of Scientists for Social and Environmental Responsibility (DEU)	(14) BIO (USA) (15) European Forum of Farm Animal Breeders and European Poultry Breeders (BEL) (16) Oxitec Ltd (GBR)	(17) American Anti-Vivisection Society (USA) (18) Center for Food Safety (USA) (19) Food & Water Europe (GBR) (20) Eurogroup for Animals (BEL) (21) Testbiotech/ FOE Europe (DEU) (22) Compassion in World Farming (GBR) (23) Animal Rights Sweden (SWE) (24) GeneWatch UK (GBR) (25) Irish Doctors' Environmental Association (IRI) (26) GM Freeze (GBR) (27) France Nature Environment/GIET (FRA)	(28) Vet from Lockport Animal Hospital (USA) (29) no (on behalf of Food & Water Europe) (USA)

Note: Participants organised by type using names and geographical location provided by EFSA (2012a) and a personal communication through EFSA's 'Ask EFSA' mechanism (email received 04/03/14).

In February 2012, EFSA published the final '*Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare*' and in May 2013,

it published the final ‘*Guidance on the environmental risk assessment of genetically modified animals*’. Along with each of these documents, EFSA published comments from the public consultations on the draft Guidance and explained how these comments had been addressed (EFSA, 2012a, 2013b).

### **3. Tensions in consulting the public in developing scientific risk assessment policy**

A number of tensions arise from the opening up of the ESFA process through public consultation. In this section, we examine each of the four tensions identified in the literature and analyse them for the case of GM animals risk assessment policy development.

#### *3.1. The tension between the goals scientific excellence and openness and transparency*

EFSA is guided by a set of key values that include scientific excellence and openness and transparency (EFSA, 2013d). EFSA defines scientific excellence as “objective and independent science-based advice grounded in the most up-to-date and reliable scientific information and data available” (EFSA, 2013d, ‘Excellence in science’) and makes a structural separation between stakeholders, publics and experts with the explicit goal to ensure scientific excellence and independence. At a management level, this distinction can be seen between the Stakeholder Consultative Platform<sup>6</sup> and the Management Board<sup>7</sup> with the Stakeholder Consultative Platform consisting of stakeholders and the Management Board composed mostly of scientific experts. In the case of the development of a risk assessment policy for GM animals, this separation can be seen in the distinction between, on the one hand, the public and stakeholders through the public consultations and, on the other hand, experts through the GMO and AHAW Panels, expert working groups, and expert workshops.

Contemporaneous with the pursuit of the goals of scientific excellence, EFSA pursues the goal of openness and transparency. Transparency is enshrined in Articles 38 and 39 of

EFSA's Founding Regulation (EC Regulation No 178, 2002) and deemed to allow stakeholders and the public to understand the basis for risk assessment, facilitate informed debate and promote public confidence in EFSA's work. EFSA's commitment to openness and transparency includes making data accessible to interested parties, opening meetings to observers, consulting the public and publishing key documents and minutes from meetings (EFSA, 2013d.). In the case of GM animals risk assessment policy, openness and transparency includes making available information about experts on the Panels and working groups and publishing the minutes of Panel and working group meetings, although the minutes of working group meetings do not include information on the substance of the meetings.

Public consultations are a policy tool that EFSA uses to achieve both of these goals, increasing scientific excellence in the risk assessment policy and opening-up the process to public scrutiny. In *EFSA's approach on Public Consultations on scientific outputs* (EFSA, n.d.), EFSA states the purpose of the public consultations in relation to the two goals of transparency and scientific excellence: "The importance of public consultations to ensure that EFSA is seen, and perceived, as a glass house is apparent and inherent to the concept of transparency... In addition, consulting on draft scientific outputs are also important in gathering views, data sources and comments that should in turn ensure the completeness, the clarity and the effective respect of those outputs." (EFSA, n.d., p. 3). However, the consultations present a challenge for EFSA as they explicitly seek input from stakeholders and the public, potentially allowing values, particularly through interests, to shape scientific outputs and this may if permitted undermine scientific excellence (the specific issue of protecting science from interests is addressed in the next section). Therefore, EFSA has to find a way to consult the public and stakeholders while ensuring that the evidence provided is

scientifically independent if it is to be used in the development of scientific outputs. Further, there are two assumptions that underlie this tension. The first assumption is that the balancing of scientific excellence, openness and transparency assumes a clear distinction between science and values and that it is possible to ensure science is free of values. This assumption is addressed in Section 3.3., below. The second assumption is that there is an opportunity to address non-scientific issues which fall outside of EFSA's remit. This assumption is addressed in Section 3.4.

This tension between the goals of scientific excellence, on the one hand, and openness and transparency on the other has been well documented (SCHER et al., 2013; Bengtsson & Klintman, 2010; Klintman & Kronsell, 2010; Oels, 2006). In 2013, the Commission's Scientific Committees published recommendations on how to improve the relevance of risk assessment in Europe (SCHER et al., 2013). The Scientific Committees called for an 'opening up' of risk assessment to include dialogue between risk managers, risk assessors and stakeholders. However, since dialogue and interaction between risk managers, risk assessors and stakeholders might undermine the independence of science through the influence of politics, so far EFSA has kept risk assessment and risk management separated. The Scientific Committees are acutely sensitive to this possible critique and throughout their report make it clear that risk assessment needs to be maintained as a scientific exercise. As stated, dialogue should take place while "ensuring the scientific integrity of the risk assessment" (SCHER et al., 2013, p. 8) and that dialogue "should properly inform but not bias what is measured in risk assessment" (SCHER et al., 2013, p. 10).

In the case of EFSA's development of risk assessment policy for GM animals this tension was managed by prioritising the key value of scientific excellence over openness and transparency and by prioritising expert knowledge over public and stakeholder knowledge. In

this way, openness was constrained and the effectiveness, as well as the legitimacy, of efforts to open up risk assessment policy to public input is drawn into question. For example, EFSA used experts from the GMO and AHAW Panels and working groups to analyse the public's comments and decide which of these counted as impartial, objective scientific knowledge. This approach attributes authority to experts to determine what counts as scientific knowledge and a two-tier system develops, privileging expert judgement over the legitimacy of public and stakeholder input (Klintman & Kronsell, 2010).

A good deal of the consultation participants (in Tables 2 and 3, see government departments/agencies, university/research organisations, industry and public interest groups) contributed scientific arguments and scientific expertise that presented alternative views to the EFSA experts as laid out in the draft Guidance documents. These comments often disputed the expert determination of what counts as sufficient evidence for risk assessment, the type of evidence relied upon and the scientific basis for the comparison of GM animal with non-GM surrogates. For example, the Federal Agency for Nature Conservation, a government agency, disputed the experts' determination that experimental data about abiotic interactions should only be provided by applicants if it is available, arguing that this data is essential for assessing these types of risks. However, in the final Guidance, the expert's determination remained. The dominance of expert knowledge and also the lack of opportunity to debate or deliberate on these scientific disputes between experts and stakeholders may be seen to undermine the scientific value of consultation.

Management of the tension between scientific excellence, openness and transparency by prioritising selected expert knowledge over public and stakeholder knowledge has been identified elsewhere. In a study of the European Environment Agency (EEA), Waterton and Wynne (2004) show that while the EEA recognised the value of opening up science policy to



new forms of deliberation, to protect its own legitimacy as a science body, it could not completely let go of the dominance of scientific knowledge and experts. However, this approach may draw into question the effectiveness and legitimacy of efforts to open up risk assessment policy to public input. For example, in a report of an EFSA workshop, Gaskell et al. (2007) characterised EFSA's public consultation approach as a 'sound science' type of public dialogue where EFSA listens to the public but does so in terms of EFSA's definition of the problem and its possible solutions. The externals' views are heard only in so far as they talk in terms of EFSA's scientific remit and hence this may undermine commitment to the outcome of the consultation.

### *3.2 Protecting the independence of expert science advice*

An important dynamic that is identified when opening up risk assessment is whether this process will create interactions between EFSA Panel members and externals that may be deemed as unacceptable access or influence. Many public and private organisations are increasingly being scrutinised for potential conflicts of interest. Public regulatory bodies are particularly sensitive to these concerns and are striving to embed governance approaches to significantly reduce conflicting relationships for staff and appointed members. An analysis conducted by Klintman & Kronsell (2010) identifies the potential for science to be shaped through interest-driven associations with stakeholders as a dependence that EFSA needs to avoid. As part of the implementation of its founding principles EFSA applies two approaches to manage interest conflicts, specifically selecting (i) what are defined to be 'independent scientists' using self-declaration protocols to identify and manage interest conflicts (as do other Commission bodies) and (ii) controlled management of the interactions between the scientific expert panels and the stakeholder panel. For example, EFSA developed an organisational structure which separates panel scientists from members of the Stakeholder

Consultative Platform, who unlike the scientists are defined as promoting interests. The need to avoid dependence and maintain the integrity of scientific advice is regularly acknowledged with independent science being seen as is an ideal that EFSA pursues.

However, the attainment of independence from interests through structural measures has been called into question not only by researchers (Klintman & Kronsell, 2010) but by the EU's own oversight body, the European Court of Auditors (ECA) (European Court of Auditors, 2012). In a recent ruling the ECA noted that EFSA is one of the EU's agencies with the greatest impartiality risk and that EFSA's Management Board involvement with external experts and partnerships with stakeholders present an inherent conflict of interest risk.

EFSA has developed several policies to address these risks<sup>8</sup> as exemplified by the 2012, announcement from EFSA's Executive Director, Ms. Geslain-Lanéelle (2012) stating EFSA had in place a number of measures to assure scientific outputs are based on transparent, open and unbiased scientific decision-making processes.<sup>9</sup> EFSA describes these mechanisms as identifying, assessing and managing conflicts of interest, collective decision-making to reduce the influence of single experts, recording minority opinions, inter-disciplinarity and multi-disciplinarity of scientific panels and committees, absence of hierarchical links between experts, training on conflicts of interest, ethics and integrity and transparency of expert meetings and guidance in risk assessment decisions (European Court of Auditors, 2012; Geslain-Lanéelle, 2012). In operationalising these principles, one of the mechanisms that EFSA still heavily relies upon is the 'Declaration of Interest' policies and procedures to protect the independence of science. This is managed by experts declaring their relevant activities and then these are subsequently screened by EFSA, so that conflicts of interests can be assessed and managed. An interest is defined as "all interests falling within fields of competence of the Authority" (EFSA, 2012b, p. 4). If a conflict is found, the expert may not

be considered for membership or restrictions may be put into place to limit her/his influence (Gassin et al., 2012).<sup>10</sup>

The effectiveness of EFSA's ability to ensure the independence of science from the threat of interests through 'Declaration of Interest' has been questioned in recent years by both EU bodies and public interest groups. The recent investigation of conflicts of interests within EFSA investigated by the European Court of Auditors (2012),<sup>11</sup> the European Parliament Committee on Budgetary Control<sup>12</sup> (2012) and the European Ombudsman (2013)<sup>13</sup> appear to highlight significant concerns that the current system may not be fit for purpose. In addition, European pressure groups GeneWatch UK, Testbiotech, Berne Declaration, SwissAid, and Corporate Europe Observatory (2012) mounted public campaigns to highlight what they perceive to be interest conflict amongst EFSA's GM animals risk assessment policy experts.

EFSA asserts that it is possible to obtain independent and objective science through structural measures; however the current reliance on a 'Declarations of Interest' approach as the primary mechanism for protecting scientific outputs from interests appears to be undermined by the recent conflicts of interest cases. Work in other sectors highlights the limits of the 'Declarations of Interest' management strategy (Cain & Detsky, 2008; Sismondo, 2008). For example, a study by Cain, Loewenstein & Moore (2005, p. 22) found that "disclosure cannot be assumed to protect recipients of advice from the dangers posed by conflicts of interest".. For an EU agency with a central role in governance of controversial areas of food production, embedding, reviewing and revising mechanisms that establish and maintain public trust is paramount. The current approaches for conflict of interest appear to be falling short of this and therefore new approaches may be needed. The 'opening-up' of the risk assessment approach rather than causing the inappropriate introduction of interests may have revealed other forms of conflict of interests. Ultimately what this may highlight is that it is

not possible in practice to constructively isolate science from interests and therefore new approaches may be called for such as innovative forms of ‘opening-up’ that allow interests to be transparent and openly debated when policy decisions are taken.

### *3.3. Recognising value judgments in risk assessment*

EFSA does not officially recognise that the science used in risk assessment involves value-based decisions despite a growing body of literature demonstrating the science of risk assessment is shaped by implicit values (e.g. Finardi et al., 2012; Wickson & Wynne, 2012; Klintman & Kronsell, 2010; Meghani, 2009; Wandall, 2004; Kunreuther & Slovic, 1996; National Research Council, 1996; Brunk et al., 1992). It has been argued that it is precisely this institutional denial of implicit values that is the cause of the public’s lack of trust in science governance (Wynne, 2006). In 2012, Wickson and Wynne (2012) outlined how the processes of scientific risk assessment are inevitably shaped by normative commitments and argued for addressing this reality “in an enlightened and accountable way” (2012, p. 101). In response, a group of authors, representing EFSA’s GMO Panel, did not acknowledge or engage with the matter of implicit values, but rather insisted that EFSA’s risk assessment is an objective scientific process (and therefore free of values) and risk management (the responsibility of the Commission and Member States) is where value choices are made (Perry et al., 2012). This position led Wickson and Wynne (2012) to claim that normative choices are being made in EU agricultural biotechnology policy under the misrepresented name of pure science.

Implicit values may shape risk assessment through bias, self-interest or research practices (Begley, 2013; Fanelli, 2012, 2009). Ian Boyd (2013), Science Advisor for the UK’s Department of Environment, Food and Rural Affairs, recently commented in *Nature* about the prevalence of bias and unreliability in scientific research literature, arguing that his role in

advising policy-makers is made significantly more challenging by inaccuracies in scientific research: with bias rendering the scientific literature ineffective for policy-making. Boyd suggests bias may arise from scientists' tendency to treat different studies as statistically independent, not to publish 'negative' results and to make statistical inferences, particularly when research is conducted on complex issues such as the environmental effects of GMOs. He also suggests that bias may be systematic across "whole fields of science" (Boyd, 2013, p. 159).

In the case of the risk assessment policy for GM animals, the Guidance documents include normative questions, assumptions and commitments which result in values playing a role in shaping the risk assessment. Interestingly, in the Guidance on environmental risks, EFSA recognises that risk assessment involves subjective judgements, but that these values can be managed through uncertainty analysis:

"In all cases, applicants' uncertainty analysis should be conducted and presented in a reproducible manner ... This is particularly important where extensive subjective experts' judgements have been applied. Subjective judgements can introduce uncertainty in model structure and parameter values, particularly in data-poor situations." (EFSA, 2013a, p. 43).

Consultation participants raised concerns about value judgements in the risk assessment policy for GM animals. For example, the Norwegian university/research organisation, GenØk Centre for Biosafety argued that applicants who wanted to release a GM animal were being asked to make explicit value judgements that should be the responsibility of risk managers. In particular, it pointed to an instance where applicants were asked to determine the significance of harm and acceptability of risk. Nine instances in the *Guidance on environmental risk assessment for GM animals* where applicants are asked to make such a determination are set

out in Table 4. EFSA's Founding Regulation and the European Commission's Scientific Committees clearly state that the determination of acceptable risk is a value-based, risk management decision (SCHER et al., 2013). Further, GenØk argued that the problem formulation stage of the risk assessment policy involves value decisions about protection goals and assessment endpoints that will guide the risk assessment process and therefore this stage should be opened up to risk managers and stakeholders (EFSA, 2013b, p. 40). This view is echoed by the Commissions Scientific Committees (SCHER et al., 2013).

**Table 4. Instances where applicants are asked to conclude on levels of acceptable risk**

	Direct quotes from the ' <i>Guidance on the environmental risk assessment of GM animals</i> '
1	However, it is vital that both the GM and comparator can be reared without unacceptable risk of mortality or adverse welfare issues. Care should be taken to choose an experimental design that does not suffer unduly from loss of animals during the experiment. (p. 36)
2	Applicants should describe ... why identified environmental impacts are considered acceptable and do not present risks. (p. 65; p. 87)
3	In addition, applicants should explain why identified environmental impacts are considered acceptable and do not present risks. (p. 67)
4	Applicants should conclude on the relative significance and acceptability of any associated environmental harm. (p. 69; p. 107)
5	Risk assessment should determine ... (5) why the impacts of the management measures and any anticipated or unintended changes to to populations, together with their uncertainty, are considered acceptable. (p. 95; p. 104)
6	Applicants should propose management/mitigation measures to reduce the risks to an acceptable level of environmental harm. (p. 106)
7	It is important that applicants ensure that their risk assessment concludes on all of the following: ... (4) why any anticipated harm may be considered acceptable. (p. 121)
8	Applicants should explain if identified environmental impacts are considered acceptable and do not present risks and the reasons thereof. (p. 134)
9	Applicants should propose appropriate risk management strategies for each risk. These strategies should be designed, under assumptions of high exposure scenarios, to reduce the risk to a level considered acceptable (criteria defining this acceptability should be explicitly discussed). (p. 153)

EFSA's public consultations present an important opportunity to identify and discuss value judgements that are made in the context of risk assessment. Indeed, Finardi et al. (2012) argue that it is precisely these implicit value judgements that present the strongest argument for EFSA's public involvement approach. By denying both the existence of values in risk assessment and the opportunity to discuss them, EFSA's values are insulated from criticism and debate. Klintman & Kronsell (2010) questioned the underlying purpose of EFSA's public consultations on scientific outputs, suggesting the primary driving force behind the shift toward good governance has been to increase public trust through increased legitimacy. EFSA has clearly stated that public consultation on "sensitive issues", such as new technologies "is considered essential to encourage the understanding and acceptance of EFSA's scientific work." (Gaskell et al., 2007, p. 2). The recent instances of institutional denial of values in risk assessment and statements like these that suggest that EFSA may see

public consultations as best serving its risk communication function rather than its risk assessment function appear to be contrary to the good governance agenda that EFSA is striving to achieve.

### *3.4. Where are ethics and social issues discussed?: The tension between risk assessment and risk management*

EFSA's Founding Regulation makes a clear distinction between the three components of risk analysis: assessment, management and communication. EFSA has responsibility for risk assessment and communication whereas risk management is the responsibility of the European Commission, specifically the Directorate-General for Health and Consumers (DG SANCO) and Member States (Gassin, Arcella, Sheye, Ramsay & Kalaïtzis, 2012; Perry et al., 2012). However, this structural separation of risk assessment from management appears to be increasingly at odds with open and accessible governance approaches, particularly when there is no notable forum for debate on risk management issues. Further, tensions arise when EFSA blurs the lines in practice between risk assessment and management while still embedding a distinction in its public consultations. Overall, the absence of a European Commission-led forum to debate the social and ethical issues raised by GM animals leads to public and stakeholder frustrations with EFSA's consultation process and risks the legitimacy of EU governance of GM animals more broadly.

In 2007, EFSA held a workshop to investigate consumer perceptions of food products from cloned animals. The workshop explored a social scientific approach to risk, particularly the social scientific evidence that public perceptions of risk are unlikely to be based on science alone, but will also be based on 'other factors' that include substantive ethical and procedural justice issues, trust, and culture (Gaskell et al., 2007). The report of EFSA's workshop draws attention to two cultures of risk, a science-based one, embraced by EFSA, and a societal one,



based on a broader range of considerations. To relieve the tension between the two cultures of risk, the EFSA's workshop report recommends that parallel social dialogues should be held to map the broader range of issues: "While retaining the independence of scientific risk assessment a social dialogue should map the other factors that are likely to drive public perceptions, recognize that consensus across the publics of Europe may not be possible and ensure that all decisions are fully justified and the reasons for rejecting certain positions fully explained. For EFSA and DG SANCO, the reality and appearance of procedural justice should be a priority." (Gaskell et al., 2007, p. 5).

EFSA's workshop on animal cloning was explicitly convened to investigate the risk management issues associated with animal cloning, including the ethical and social issues. At the time, it was stated that exploring these issues "would help to better understand and anticipate societal views and set a context for EFSA's scientific work." (Gaskell et al., 2007, p. 2). This blurring of the line between risk assessment and management sends a confusing message to stakeholders and the public who are not allowed to comment on risk management issues in EFSA's public consultation, even though EFSA itself sees the issues as important for setting a context for its work. Indeed, EFSA's Director of Communications states "Experience ... shows that ... ethical considerations must also be taken into consideration and that public consultation and stakeholder engagement are critical for informed discussion on sensitive technologies." (Gassin et al., 2012, p. 390).

EFSA's Founding Regulation recognises: "scientific risk assessment alone cannot ... provide all the information on which a risk management decision should be based, and that other factors ... should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors." (EC Regulation No 178, 2002, p. 4). However, it is not clear that DG SANCO has created a mechanism at the EU level for debating or understanding

these risk management issues related to GM animals. The case of animal cloning for food production presents a useful example of what is possible procedurally when developing EU governance structures for emerging agricultural technologies. In the case of animal cloning, the Commission requested a scientific opinion from EFSA, an ethical opinion from the Group of Advisers on the Ethical Implications of Biotechnology (EGE) and a public survey through the Eurobarometer. In 2010, the Commission made a decision based on an analysis of these three inputs (European Commission, 2010).<sup>14</sup> Furthermore, in 2012, the European Commission held a public consultation to flush out stakeholder and public views on animal cloning for food production, including the economic, social and environmental issues as it considered further policy and legislative options for animal cloning for food production (European Commission, 2012).

The Commission requested an ethical opinion on GM animals from the EGE in the early 1990s. In 1996, the EGE published its *Opinion on the Ethical Aspects of Genetic Modification of Animals*. However, more than twenty years later, this Opinion is out of date with technological developments that have taken place in the area of GM animals and focused on the use of transgenic methods for the development of experiment animals. In addition, this report does not consider GM insects, currently predicted to be the first GM animal to pass through the risk assessment process (Environment Agency Austria, 2010), and there is no evidence that this document has played a role in the development of the current EU governance framework for GM animals.

Despite the specified terms of reference for EFSA's public consultations that restricted comments to scientific issues, participants addressed the ethical and social issues and communicated their frustration about EFSA's inability to consider these issues. Participants raised concerns about procedural legitimacy, including the false separation of science from

the ethical and social issues, the lack of space to debate these issues and what was described as the premature scientific risk assessment when the social and ethical issues had not been debated in the broader policy framework. Some participants saw the consultation as evidence of the European Commission's acceptance that GM animals were desirable without allowing for public debate of the full range of issues. Table 5. documents participant concerns about procedural legitimacy in the public consultation on *Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare*. However, EFSA did not consider these issues as they fell outside its remit "Many comments referred to lack of a holistic approach including ethical, political and socioeconomic issues ... These comments were considered to be outside the scientific remit of EFSA and were not addressed." (EFSA, 2012a, p. 5).

**Table. 5. Stakeholder concerns about procedural legitimacy**

<b>Quotes from ‘Outcome of the public consultation on the draft scientific opinion of the Scientific Panels on GMO and on AHAW on the Guidance on the risk assessment of food and feed from GM animals and on animal health and welfare aspects’ (EFSA, 2012a)</b>	
<b>France Nature Environment/GIET</b>	
All online consultations launched by EFSA are in English, which is not the only official language of the EU. This is contrary to the Charter of Fundamental Rights ... and prevents a large part of European citizens from taking part in these online consultations. (p. 25)	
On p.40, the guidance presents several reports and indicators to assess animal welfare. The animal welfare is a complex concept that includes scientific, ethical but also economic, cultural and political issues. (p. 74)	
Providing guidance for the risk assessment ... implies that general issues, including ethical and socio-economics issues, have been previously debated, to decide whether or not genetic modification of animals can be done. (p. 25)	
<b>The Norwegian Biotechnology Advisory Board</b>	
When doing risk assessments for genetically modified animals, ethical and socio-economic issues must be taken into account in the assessment. Issues concerning ethics, sustainability and benefits to society are just as important here as when it comes to GM plants. (p. 26)	
<b>Food &amp; Water Europe</b>	
Risk management and socioeconomic issues are neglected in the discussion of risk assessment for GM animals. (p. 16)	
The EFSA (GMO and AHAW) panels ... have chosen not to include some of the most important issues surrounding GM animals in their risk assessment guidance including risk management issues such as traceability, labelling and coexistence, and ethical and socioeconomic issues. As such, the process is fatally flawed. Neglecting to take a look at the full range of issues surrounding approvals of GM animals is unwise, is not in line with the EU’s guiding precautionary principle and renders this exercise so flawed its results will be of questionable value. (p. 26)	
Also notably missing from the risk assessment considerations are ethical and moral issues surrounding genetic modification of animals. (p. 26)	
<b>GM Freeze</b>	
We do not believe that it is a sensible approach to compartmentalise issues of science , ethics, environmental impact, socio-economics and animal welfare because final decisions to approve (by politicians) or purchase (by farmers and consumers) should not be based solely on science and seldom are. No decisions about farming and food chain are ever based on science alone and never should be. (p. 40)	
<b>Compassion in World Farming</b>	
The summary says: “The question to be answered is whether there are problems in the health and welfare of GM animals”. Whilst this is an important question, it is not the fundamental ethical question, which is: “Should we genetically modify animals who are being reared for the production of food or feed?” Until this latter question has been answered – and answered in the affirmative – the statement referred to above is premature. (p. 24)	
(We) believe that the question we posed in the first paragraph ... [Should we genetically modify animals for food and feed?] ... should be referred urgently to the Ethical Group of Advisors in Science and New Technologies for an Opinion. (p. 24)	
<b>Ministry of Rural Development of Hungary</b>	
The social, ethical and religious considerations of introducing GM animals and animal products are missing from the risk assessment. (p. 17)	
<b>American Anti-Vivisection Society</b>	
A robust risk management process, one which includes ethical considerations, will also be necessary to protect animal interests and the public’s interest in animal welfare. (p. 23)	
<b>GeneWatch UK</b>	
EFSA appears to want to begin at the point of assuming production is ethical and acceptable. This Guidance is premature until these important issues have been addressed. (p. 27)	
<b>Animal Rights Sweden</b>	
It is a great lack that the ethical aspects are not at all addressed in this guidance document. Ethical aspects are important and should not be excluded in discussing animal welfare and health. (p. 39)	

A number of pressure groups have called for debate on the ethical and social issues for GM animals, for example, Friends of the Earth Europe, Test Biotech, Euro Coop, Eurogroup for Animals, European Milk Board and IFOAM EU Group (2012) submitted an ‘open letter’ to Commissioner Dalli raising concerns about the lack of public debate. Some of these NGOs and others took advantage of EFSA’s public consultations to submit comments that addressed ethical and social issues. It appears that the lack of opportunity for stakeholders and the public to debate the social and ethical issues elsewhere in the governance framework has led to increased frustration with EFSA’s public consultation and the risk assessment output *per se*.

At this time, the governance framework for GM animals consists of EFSA’s risk assessment policy and is based solely on science. Brunk & Hartley (2012) have drawn attention to the risk to legitimacy that results from democratic mechanisms relying solely on science. These risks were also discussed at the EFSA workshop on animal cloning for food production where Gaskell et al (2007) note: “if risk managers do not recognize the import of ‘other factors’ then EFSA’s science based position may come into conflict with public perceptions... In such a situation trust in EFSA and other EU bodies may be jeopardised” (p. 5).

#### **4. Conclusion**

This policy process presents an important case for examining the tensions between the scientific and technical remit of public agency and the aims and expectations within the public consultation process. EFSA’s approach to public consultations acknowledges stakeholder and public knowledge as legitimate and recognises that this knowledge may improve the quality of risk assessment, but there are clear limitations to the way in which

EFSA operationalises governance commitments and policies. First, EFSA must operate within its statutory remit and therefore can only consult the public on the scientific aspects of risk assessment policy, although there is evidence that EFSA has blurred the lines of its remit by considering the social and ethical issues in other cases. Further, EFSA clearly limits the type of knowledge it accepts through its refusal to acknowledge value judgements in risk assessment. What might be seen as democratisation of expertise through the inclusion of the public in risk assessment, does not appear fit for purpose as it limits the type of knowledge which is deemed as acceptable to inform risk assessment and this appears out of step with public understandings of what should be considered in risk governance approaches.

The European Commission's Scientific Committees suggest that the tension between opening up risk assessment and managing the integrity of the scientific process could be handled through greater transparency (SCHER, 2013). However, our analysis of the case of risk assessment policy for GM animals suggests that as well as addressing transparency issues, creating a space for debating the broader risk management issues may be needed alongside the EFSA's consultation. The EFSA public consultation policy tool presents a valuable and innovative opportunity to flush out the value judgements embedded in risk assessment and debate them in a way that can strengthen food safety governance. However, the public consultations on developing a risk assessment policy for GM animals appear to have drawn out some deep rooted frustrations with the boundaries set by EFSA and a lack of an alternative forum to debate the broader policy issues which could be said to fall under DG SANCO's remit. Although EFSA's Founding Regulation makes a clear distinction between scientific risk assessment and risk management, it also makes explicit the need for coherence between the three stages of risk analysis: assessment, management and communication. The Founding Regulation demands a strong relationship and close cooperation between risk

managers and EFSA to ensure this coherence (EC Regulation No 178, 2002). It would seem as though closer cooperation on public consultation is required to allow the public to provide input on the full range of issues related to risk governance of GM animals. Further work exploring the expectations and concerns of the key actors in this governance system should provide valuable data that could support future policy developments that strengthen and enhance, rather than reduce, this important institution's legitimacy.

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<sup>1</sup> Risk assessment is defined in EFSA's Founding Regulation as "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation" (EC Regulation No 178, 2002, p 11).

<sup>2</sup> Risk assessment policy is defined by the Codex Alimentarius Commission as: "Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained" (CAC, 2013, p.114).

<sup>3</sup> These are Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

<sup>4</sup> There is considerable international interest in GM insects. Their role in agricultural production and global food security was the focus of a U.S. Department of State Roundtable in 2013. In the EU, the majority of GM insects in agriculture are being developed for population suppression, containment and elimination, predominantly in the production of olives, tomatoes, citrus fruits, cabbages and cotton. The hope is that GM insects will improve existing population suppression, containment and elimination methods in agricultural production. Field trials for agricultural GM insects began in the United States in 2001, although an applications to release GM agricultural insects in Europe were made in Spain in 2013 and the UK in 2011 (in both cases more information was requested from the applicant about the risks).

<sup>5</sup> The Scientific /Technical Reports for EFSA's environmental risk assessment policy for GM animals are: 1] *Defining Environmental Risk Assessment Criteria for Genetically Modified Insects to be placed on the EU Market* (Environment Agency Austria, 2010); 2] *Defining Environmental Risk Assessment Criteria for Genetically Modified Fishes to be placed on the EU Market* (University of Hull International Fisheries Institute, 2010); and 3] *Defining Environmental Risk Assessment Criteria for Genetically Modified Mammals and Birds to be placed on the EU Market* (Food and Environment Research Agency, 2011).

<sup>6</sup> The Stakeholder Consultative Platform is composed of EU-wide organisations with interests related to EFSA's remit and provides advice to EFSA on matters that include management and risk assessment methodologies (Gassin et al., 2012).

<sup>7</sup> The Management Board ensures EFSA functions effectively and efficiently. Members of the Board are selected based on their experience and expert scientific background. Four of the 15 Management Board members come from and are active in stakeholder organisations (EC Regulation No 178, 2002).

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<sup>8</sup> The most pertinent of these policies are the *Policy on Independence and Scientific Decision-Making Processes* (Adopted 2011), the *Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests* (Adopted 2012), *Management Board decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups* (Adopted 2012), and the *Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work* (Adopted 2013). These policies can be found on EFSA's website: <http://www.efsa.europa.eu/>.

<sup>9</sup> Ms. Geslain-Lanéelle was EFSA's Executive Director from July 2006 to July 2013.

<sup>10</sup> For example, hearing experts may have a conflict of interest and therefore hold no responsibilities and cannot be invited to more than 30% of Panel or Working Group meetings (EFSA, 2013c, Article 21).

<sup>11</sup> The European Court of Auditors raised concerns about possible conflicts in EFSA's Management Board, inadequate screening of experts and criteria for the evaluation of conflict of interest, inconsistencies in declaring and treating conflict of interest for members of the Management Board and experts committees, conflicting roles of experts who were advocates and reviewers of the same concepts, and questionable assessment of conflicts of interest that resulted in the failure to identify conflicts of interest when they existed (European Court of Auditors, 2012).

<sup>12</sup> In 2012, the European Parliament Committee on Budgetary Control postponed its approval of EFSA's 2010 accounts due, in part, to concerns it had over conflicts of interest. In particular, it raised concerns about reported links between the Chair of the Management Board and the food industry, links between EFSA's Board, Panels and working groups and the International Life Science Institute, an organisation that is funded by the food, chemical and pharmaceutical industries, and the Chair of the Management Board's failure to declare a conflict of interest in 2010 (European Parliament Committee on Budgetary Control, 2012).

<sup>13</sup> The European Ombudsman (2013) investigated EFSA's response to the movement of EFSA's Head of the GMO Unit and Scientific Co-ordinator of the GMO Panel, to Head of Regulatory & Stewardship Seeds at Syngenta. The Ombudsman found a conflict of interest and noted that "EFSA should acknowledge that it failed to observe the relevant procedural rules and to carry out a sufficiently thorough assessment of the potential conflict of interests" (European Ombudsman, 2013, p 16). EFSA refused to acknowledge its failings.

<sup>14</sup> The European Commission proposed a 5-year suspension of animal cloning for food production in the EU (European Commission, 2010).